DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Mr. James Komorowski
Vice President, Technical Services and Scientific Affairs
Nutrition 21
4 Manhattanville Road, Suite 202
Purchase, NY 10577

JAN 28 2005

Dear Mr. Komorowski:

This is to inform you that the notification you submitted, dated November 15, 2004, pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on November 15, 2004. Your notification concerns the substance called "Arginine silicate inositol (ASI) complex" that you intend to market as a new dietary ingredient.

The notification informs FDA that Nutrition 21 intends to distribute the new dietary ingredient, "ASI Complex" in a dietary supplement product "[I]n the form of oral tablets containing 750 mg of the Arginine:silicon:inositol complex. Similar levels of the ingredient may be used in other dietary supplement formulations." The notification further states that "[C]onsumption of 2 tablets per day will be suggested or recommended....The product label will indicate that ASI Complex is recommended for use in adults only, and that the product should not be used by pregnant or lactating women."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Based on the information in your submission, FDA was unable to determine the identity of your new dietary ingredient, "ASI Complex." For example, the structure in Figure 1 (Notification, page 2) appears to show a covalently bonded structure of arginine and silicate, although the nature of the interaction between these two substances in the complex is unclear. In addition, the formula weight of a complex consisting of 2:2:1 arginine, silicon and inositol would be expected to be approximately 837, not 324.4819 as stated in the Notification. Because the chemical description of "ASI Complex" in your notification was incomplete and inconsistent, FDA was unable to identify your new dietary ingredient.

Because FDA could not determine the identity of "ASI Complex," it is not readily apparent whether the "ASI Complex" that is the subject of your notification is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
(A) a vitamin;
(B) a mineral;
(C) an herb or other botanical:
(D) an amino acid;
(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Based on the information in your submission, it is unclear that "ASI Complex" is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1). Therefore FDA cannot determine, at this time, whether your product contains a dietary ingredient that may lawfully be marketed as a dietary supplement.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "ASI Complex," when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of November 15, 2004. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

Linda S. Pellicore

for Susan J. Walker, M.D.
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